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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/002,329 | 11/01/2001 | Aaron V. Kaplan | KAP 101 DIV | 6187 |

7590

06/29/2005

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| EXAMINER |
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MENDEZ, MANUEL A

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| ART UNIT | PAPER NUMBER |
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3763

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/002,329 | Applicant(s) KAPLAN ET AL. | |
| | Examiner Manuel Mendez | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>04/27/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

SUPPLEMENTAL DETAILED ACTION

The examiner of record acknowledges receipt of the Response to Notice of Drawing Inconsistency on April 8, 2005. However, it appears that applicant did not receive the present office action sent on March 22, 2005. Accordingly, the examiner of record is resending this office action for applicant's review and response.

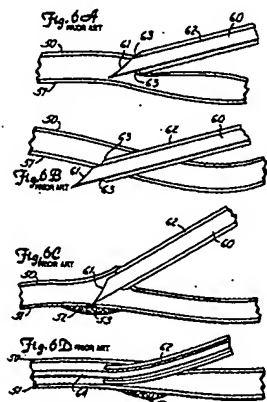
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

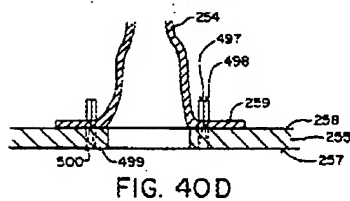
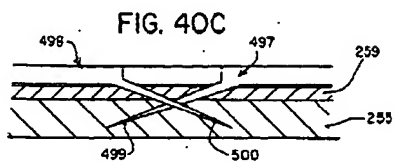
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Amplatz, et al. in view of Gifford, III et al. and in further view of Cohen.**

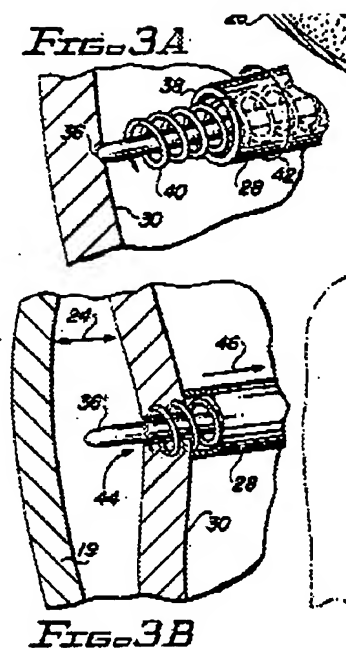


The Amplatz, et al., patent shows in figures 6A-6D, an access tube (62) having a distal end (63) which can be selectively embedded into tissue, and a needle (61) having a lumen and being configured to pass through the access tube (62) and penetrate into the anatomic space wall, and a guidewire (64).

Amplatz, et al., does not disclose an anchor at the distal of the access tube comprising one or more penetrating points. However, the use of penetrating points in combination with access tubes is conventional as evidenced by the teachings of Gifford III, et al., and Cohen.



Gifford III, et al., shows in figures 40A-40D, the use of an anchor structure at the end of an access device. The anchor structure (497) comprises of penetrating points (499,500).



The Cohen patent shows in figures 3A and 3B, anchoring means at the distal end of access tube (28). Notably, figure 3B illustrates the conventionality of using anchoring means to enhance the accuracy of the access tube in relation to the body tissue. Additionally, the figure demonstrates how pulling the access tube in a proximal direction (46) after the insertion of the anchoring means into tissue, facilitates the manipulation of tissue layer (30).

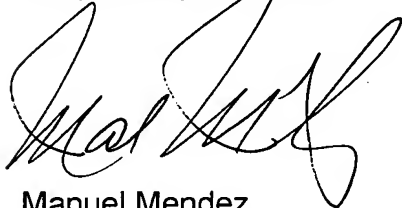
Based on the teachings of Gifford, III et al., and Cohen, it would have been obvious for a person of ordinary skill in the art to modify the apparatus in Amplatz, et al., with anchoring means in order to enhance the accuracy of the access tube in the cutting of tissue. Conclusively, the use of anchoring devices in combination with an access tube or cannula would have been considered an obvious design alternative.

Art Unit: 3763

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Manuel Mendez', with a stylized, cursive script.

Manuel Mendez
Primary Patent Examiner
AU 3763